In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 13-122V

Filed: November 13, 2015

[TO BE PUBLISHED]

ANDREW RODD,	*	
	*	
Petitioner,	*	
	*	
v.	*	Influenza vaccine; Overlap Syndrome;
	*	Sjogren's Syndrome; Polymyositis;
SECRETARY OF HEALTH	*	Inflammatory Arthritis.
AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	

Lawrence R. Cohan, Anapol Schwartz, et al., Philadelphia, PA, for petitioner.
Gordon E. Shemin, United States Department of Justice, for respondent.

RULING ON ENTITLEMENT[1]

Gowen, Special Master:

On February 15, 2013, Andrew Rodd ("petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10 – 34 (2012)[2] (the "Vaccine Act" or "the Program"). Petitioner alleged that as a result of receiving the influenza ("flu") vaccine on September 14, 2011, he developed numbness and tingling in his hands due to the aggravation of an underlying, asymptomatic carpal tunnel syndrome, and that

[1] Because this published ruling contains a reasoned explanation for the action in this case, I intend to post it on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to delete medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will delete such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

over the course of weeks after the vaccine, his condition evolved into symptomatic polyarthritis, polymyositis, inflammatory arthritis, and Sjogren's syndrome. *See* Petition at Preamble.

Petitioner has proffered both medical records and expert medical opinion providing a theory of a causal link between his flu vaccination and injuries, as well as a logical cause and effect explanation for the causal relationship. Petitioner's expert also supported the appropriateness of the timing of onset of his condition. Respondent has countered with an expert medical opinion. Both parties submitted extensive medical literature.[3] Petitioner continues to suffer from these conditions.

Petitioner contends that his diagnosis was overlap syndrome consisting of polymyositis, Sjogren's syndrome, and inflammatory arthritis, as diagnosed by his treating physicians. Petitioner's expert testified that Mr. Rodd likely experienced initial symptoms of carpal tunnel syndrome the day after the vaccine as a result of an innate cytokine response to the vaccine, but subsequently, approximately several weeks later, began to experience significantly different symptoms of weakness in his shoulders, arms and legs which became progressively worse with the addition of swelling and pain in multiple joints. Respondent countered that the evidence was more consistent with anti-synthetase syndrome with a date of onset the day after the vaccination. Both experts agreed that whether Mr. Rodd had overlap syndrome or anti-synthetase syndrome was not relevant to their disagreement as to causation. Rather, the basis of the disagreement was the date of onset of the rheumatological disease and the nature of the earliest symptoms—that is, whether they were symptoms of carpal tunnel syndrome or early polyarthritis.

For the reasons stated herein, I find that petitioner has provided sufficient evidence to demonstrate that Mr. Rodd initially suffered an inflammatory aggravation of the carpal tunnel syndrome which became symptomatic the day after the vaccine, and which was subsequently relieved by carpal tunnel surgery. This aggravation was secondary to an innate response to the vaccine. In addition, two to three weeks later he developed an autoimmune disease, either overlap syndrome or anti-synthetase syndrome, triggered by the flu vaccine. Accordingly, I have concluded that petitioner is entitled to compensation.

I. Procedural History

This case was filed on February 15, 2013, and assigned to Special Master Moran. Along with the petition, petitioner filed an expert report from Vera Byers, M.D., Ph.D. *See* Pet. Ex. 6. In the ensuing three months following the filing of the petition, petitioner filed medical records detailing Mr. Rodd's diagnosis and treatment of "overlap syndrome consisting of polymyositis, Sjogren's syndrome, and inflammatory arthritis." *See* Pet. Ex. 1, 3-16.

[3] I have considered the entire record in arriving at my decision (§ 300aa–13(a)(1)). This includes extensive medical literature submitted by both parties which I have read and considered. I will discuss in the course of this opinion the exhibits that are most relevant to the resolution of this case.

On July 2, 2013, respondent filed her Rule 4(c) Report recommending against compensation under the Vaccine Act, asserting petitioner had not met the burden of proof to establish causation. *See* Resp. Rep. at 11. Respondent further argued that although some of petitioner's treating physicians linked his condition to the influenza vaccination, they had not provided a causal theory or otherwise explained the basis of their opinions. *Id.* Accordingly, on September 25, 2013, petitioner was ordered to file a supplemental expert report addressing the *Althen*[4] criteria and specific questions raised by the special master in a status conference with counsel. Petitioner filed a supplemental expert report from Dr. Byers on October 23, 2013. *See* Pet. Ex. 18. Respondent filed a responsive expert report from Chester V. Oddis, M.D., along with a curriculum vitae on December 9, 2013. *See* Resp. Ex. A-B. Respondent filed medical literature in support of Dr. Oddis' opinion on December 17, 2013. *See* Resp. Ex. C-H. Petitioner's second supplemental expert report from Dr. Byers was subsequently filed on March 2, 2014. *See* Pet. Ex. 19. Respondent filed a responsive expert report along with medical literature from Dr. Oddis on March 4, 2014. *See* Resp. Ex. I-K.

Thereafter, the undersigned was assigned to this case on July 18, 2014, and an entitlement hearing was held on December 11, 2014. At the conclusion of the hearing, the parties discussed with the Special Master whether there was a need to brief the case. Respondent requested time to consider whether she wished to file additional medical literature and/or to file a post-hearing brief, and an order was issued directing respondent to file a status report by December 30, 2014, indicating whether she wished to do so. The respondent filed the status report on December 30, stating that she did not wish to file additional literature or a brief. Both parties subsequently indicated that they would stand on the evidentiary record from the hearing. Therefore, the matter is now ripe for a decision on entitlement.

II. Evidentiary Record

At the hearing, Mr. Rodd testified, and Dr. Byers testified on his behalf. Dr. Oddis testified on behalf of respondent. Mr. Rodd testified that he was a farm manager on a large farm in New York where he trained show horses. Tr. at 8. In that capacity he lifted 10,000 bales of hay per year, had a Class A commercial driver's license, operated tractors, hay balers, and drove most anything. *Id*. at 37-38. His past medical history was non-contributory, with the most significant event being a lumbar discectomy in 2004 that was 100% successful. *Id.* at 36-37. He had been in relatively good health, as documented by Dr. Walker's medical records, from about 2008 to the date upon which the vaccine was given. *See generally*, Pet. Ex. 9.

The petition alleges, and Mr. Rodd testified, that he received the influenza vaccine on September 14, 2011, at the office of his family physician, David Walker, M.D., in Pine Plains, New York. Petition at ¶ 3; Tr. at 13. Mr. Rodd testified that the day after he was vaccinated he awoke with tingling in the tips of his fingers and thumbs but did not consider the symptoms significant. Tr. at 12. The following day after driving a tractor his hands were stiff. *Id.* In the first few days the symptoms were not very significant in the wrist, and were mostly in the fingers and especially the thumb joints in both hands. *Id*. at 13. During the day he did a lot of driving and noticed when he took his hands off the steering wheel they were really numb. *Id*. at 12. Several days after the vaccine he called Dr. Walker's office and spoke to the nurse who had

[4] *Althen v. Sec'y of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

given him the shot. She told him that these were very common symptoms after a flu shot and to call back if it did not wear off in a couple of days. *Id*. The symptoms were in his fingers and in the thumb joints going back into the palm of the hand (demonstrated by petitioner). *Id*. at 14. The symptoms were symmetrical. *Id*. at 13. About eight to ten days after the vaccination, with the symptoms continuing, he called Dr. Walker's office for an appointment, but could not get one until about a month after the shot. *Id*. at 13-14.

Dr. Walker's record reflects that this appointment occurred on October 18, 2011. *See* Pet. Ex. 1 at 000003. By that time there may have been some semblance of symptoms beginning in his forearms and shoulders but Mr. Rodd assumed that it was because his hands were not working properly, and he was not able to lift or handle a fork. Tr. at 16. As the condition evolved, initially Mr. Rodd was able to extend his fingers but could not flex them. *Id*. at 20. Dr. Walker's note from October 18 indicates petitioner was having difficulty using his hands, reported it came on September 15, and believed it occurred the day after his flu vaccine. Pet. Ex. 1 at 000003. Symptoms were worse at night, and gradually better during the day. *Id*. There was no swelling, neck pain, injury, or trauma. *Id*. Petitioner had decreased finger range of motion and decreased grip strength, but no edema or breathing problems. *Id*. at 000004. Dr. Walker's assessment was muscle weakness. *Id*.

After seeing him again on October 21, 2011, Dr. Walker referred petitioner to a neurologist, Misha Kucherov, M.D. Dr. Kucherov saw Mr. Rodd the same day and noted severe wrist/thumb/finger pain times one month, not all the time. Pet. Ex. 3 at 000002. In her chart she noted some weakness and pain around the thumbs, that increased stiffness in the wrists had occurred the day following the flu shot, and that symptoms were getting worse slightly. *Id*. She did a Tinel's test, which was positive, and therefore suggestive of carpal tunnel syndrome. *Id.* at 000004; Tr. 58. When asked at hearing if he could describe the symptoms that he felt in the early days after the vaccination Mr. Rodd answered that it was pins and needles in his hands. Tr. at 28-29. Blood was also drawn on October 21, which revealed an elevated SSA, but negative SSB.[5] Pet. Ex. 3 at 000005.

Dr. Kucherov referred him to Dr. Mark Bodack, M.D., for an EMG/NCS[6] of the upper limbs, which was performed on November 4, 2011. Pet. Ex. 3 at 000009. The EMG/NCS revealed that motor conduction velocities were normal except for the conduction velocities for the median nerve across the wrist, which were slowed. *Id*. at 000010. The test also showed slightly reduced SNAP amplitudes (sensory nerve action potentials), absent median sensory responses to digit I, and chronic neurogenic potentials in the FDI (first digital interosseous) and ADM (abductor digiti minimi) muscles. *Id*. Dr. Boday's diagnostic conclusions were mild to

[5] Anti-SSA and anti-SSB are antibodies associated with the diagnosis of Sjogren's syndrome.

[6] EMG is an electromyogram, which is a test that measures electrical activity in muscles. An NCS or nerve conduction study measures electrical conduction in nerves. The studies are often done together as they were in this case, and are used to identify the presence, location, and extent of damage or disease in nerves and muscles. *Health Library: Nerve Conduction Studies*, JOHNS HOPKINS MEDICINE, http://www.hopkinsmedicine.org/healthlibrary/test_procedures/neurological/nerve_conduction_velocity_ncv_92,P07657/.

moderate sensorimotor neuropathy at the level of the wrist bilaterally (carpal tunnel syndrome) without chronic axonal loss, and bilateral ulnar neuropathy versus C8-T1 radiculopathy. *Id.* His report noted that mildly reduced ulnar sensory amplitudes are consistent with the former while absence of abnormalities in the APB (abductor pollicis brevis) muscles does not completely rule out the latter. *Id.*

Mr. Rodd was then referred to a rheumatologist, Dr. Farah Ashraf, M.D., in Poughkeepsie, New York, who he saw on December 5, 2011. Dr. Ashraf noted a history of polyarthritis for ten weeks since receiving the flu vaccine, myalgias, weakness, dry mouth, no dry eyes, and SSA >8 (abnormal). Pet. Ex. 4 at 000002. She diagnosed Sicca Syndrome (also known as Sjogren's syndrome) based on the elevated SSA and petitioner's dry mouth symptoms. *Id.* Mr. Rodd was started on 60 mg of Prednisone. *Id.* Dr. Ashraf ordered additional blood work, and on December 16, reviewed the blood work with petitioner, which indicated the presence of the anti-Jo-1 antibody, and elevated Aldolase (a liver enzyme). Pet. Ex. 8 at 00096. Both results are abnormal. She diagnosed myalgia and myositis unspecified, and ordered that he remain on Prednisone 60 mg. *Id.* at 000003. Mr. Rodd testified that his muscle weakness in the shoulders began to be noticeable at about the time of the October 21 appointment with Dr. Kucherov. Tr. at 25. By the time that he saw Dr. Ashraf in early December, the muscle weakness had become much worse and had spread to the arms, shoulders, and neck, and his neck was particularly badly affected by that time. *Id.* at 26. He could not get in and out of bed without help and could not get out of the bathtub or off the toilet without help by that time because of muscular weakness. *Id.* at 27. His hips and thighs were also weak, and his knees and feet also became badly affected later. *Id.* at 28.

On follow-up on January 17, 2012, Dr. Ashraf noted that after six weeks of Prednisone, there was Sjogren's syndrome, but no muscle weakness—just numbness and tingling in his fingers/carpal tunnel syndrome. Pet. Ex. 4 at 000004. She directed that Mr. Rodd reduce the Prednisone to 40 mg and added Plaquenil. *Id.* She referred him for carpal tunnel release surgery. *Id.*

After what appeared to be some improvement, Mr. Rodd's symptoms persisted on lower doses of Prednisone, and the Plaquenil was not helpful. Pet. Ex. 4 at 000005-6. The carpal tunnel surgery was performed and helped significantly with the original symptoms of numbness and tingling in the hands. It helped a lot with driving, which was a big part of the petitioner's life. Tr. at 30-31. However, the non-carpal tunnel symptoms persisted.

Eventually, Mr. Rodd was referred to Mark Horowitz, M.D., a rheumatologist and myositis specialist in New York City. He saw Dr. Horowitz on July 25, 2012, for a comprehensive evaluation and second opinion. Pet. Ex. 5 at 000001. In his report, Dr. Horowitz recited the history of acute polyarthritis, which occurred in additive fashion beginning in September, 2011. *Id.* He reported that this condition had begun 24 hours after petitioner received a flu shot and had progressed from the wrist, elbows, shoulders, ankles, and toes, with pain, swelling and morning stiffness. *Id.* Positive Sjogren's antibodies had been detected. *Id.* Mr. Rodd had developed numbness of both hands, an EMG confirmed bilateral carpal tunnel syndrome, and he underwent bilateral carpal tunnel release with symptomatic relief, but remained impaired from many activities of daily living. *Id.* Dr. Horowitz noted that Mr. Rodd had been started on 80 mg of Prednisone by Dr. Ashraf, with good response, but developed a

marked symptomatic flare upon steroid taper. *Id*. Plaquenil had been ineffective, and Methotrexate, 8 tablets per day, had provided minimal symptomatic improvement. *Id.* Petitioner had been placed on 60 mg of Prednisone four weeks prior to his consult with Dr. Horowitz due to his inability to transfer out of a seated position, or even out of bed. *Id*.

On Dr. Horowitz's physical exam he noted synovitis of the wrist, PIP, and MCP joints of the fingers. Pet. Ex.5 at 000002. There was 3/5 proximal lower extremity strength, and 4/5 proximal upper extremity strength. *Id*. Distal strength was 5/5 in all extremities. *Id.* Saliva production was decreased but tears were present. *Id*. Mr. Rodd's CPK was elevated at 222, the anti-Jo-1 antibody was strongly positive and aldolase elevated at 8.7, but other antinuclear and rheumatological factors were negative. *Id*.

Dr. Horowitz stated that Mr. Rodd has "overwhelming evidence for an overlap syndrome with features of polymyositis, Sjogren's syndrome and inflammatory arthritis." Pet. Ex. 5 at 000002. He stated that the presence of anti-Jo-1 antibodies, the history of Sjogren's syndrome, and persistent elevations of the CPK and aldolase levels support this diagnosis. *Id.* Dr. Horowitz noted that Mr. Rodd was "profoundly weak and completely disabled from performing his occupation, as well as activities of daily living." *Id*. He had an unacceptable 40 mg maintenance requirement of Prednisone per day and Dr. Horowitz discussed Rituximab infusion therapy with him given that he was completely disabled. *Id*. Mr. Rodd agreed, and after consultation with Dr. Janet Cutner in New York, who had established a protocol for this treatment, Dr. Horowitz prescribed 375 mg per meter squared of Rituximab weekly for a total of four doses. *Id*. at 000003. The therapy was to be provided by Dr. Paul Donovan at Benedictine Hospital nearer to Mr. Rodd's home. *Id*.

On September 26, 2012, Dr. Paul Donovan, M.D., reported that Mr. Rodd had completed four cycles of Rituximab infusion therapy at Benedictine Hospital. Pet. Ex. 8 at 000048. He further reported that the treatment had not succeeded and that in fact Mr. Rodd was now in the worst situation he has been in nine months. *Id*. He was having severe pain in the joints, particularly the wrist and hand joints, as well as pain in the knees, shoulders and ankles. *Id*. He could not work to any degree and could not sleep at night. *Id*. He had little or no function in his hands, either fine manipulation or heavy lifting. *Id*.

In October 2012, Mr. Rodd was hospitalized for five days at Mount Sinai in New York City when he developed a fever and shivering while in Dr. Horowitz's office. Pet. Ex. 16 at 000033. He was also admitted to Benedictine Hospital in November, 2012, with similar symptoms and a low platelet count of 39,000. Pet. Ex. 14 at 00005-7. In both cases, bacterial and viral etiologies were sought but none were found. *See generally*, Pet. Ex. 8, 14. On November 5, 2012, Dr. Donovan reported that petitioner had the same symptom complex as before: poor grip strength, muscle weakness, particularly in hands, arms, shoulder and less so in the legs, with no other symptoms. Pet. Ex. 8 at 000059. He was on 60 mg per day of Prednisone. *Id*. On April 11, 2013, Dr. Daniel Albert, M.D., reported that Mr. Rodd had poor grip strength, overlap syndrome, proximal and distal strength 4+/5 and poor response to treatment. Pet. Ex. 14 at 000002.

III. Discussion

A. Legal Standards to Establish Entitlement to Compensation

The Vaccine Act established the Program to compensate vaccine-related injuries and deaths. § 300aa-10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" *Rooks v. Sec'y of HHS*, 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

In order to prevail under the Program, a petitioner must prove either a "Table" injury[7] or that a vaccine listed in the Table was the cause in fact of an injury (an "off-Table" injury). Petitioner alleges that he suffered non-Table injuries—autoimmune overlap syndrome consisting of polymyositis, polyarthralgia and Sjogren's syndrome. Therefore, petitioner must demonstrate by preponderant evidence that a covered vaccine is responsible for his injuries.

An "off-Table" injury is initially established when the petitioner demonstrates, by a preponderance of the evidence: (1) that he received a vaccine set forth on the Vaccine Injury Table; (2) that he received the vaccine in the United States; (3) that he sustained or had significantly aggravated an illness, disease, disability, or condition caused by the vaccine; and (4) that the condition has persisted for more than six months. § 13(a)(1)(A). To satisfy his burden of proving causation in fact, petitioner must establish each of the three *Althen* factors by preponderant evidence: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a proximate temporal relationship between vaccination and injury. *Althen v. Sec'y of HHS,* 418 F.3d at 1278; *see de Bazan v. Sec'y of HHS*, 539 F.3d 1347, 1351-52 (Fed. Cir. 2008); *Caves v. Sec'y of HHS,* 100 Fed. Cl. 119, 132 (2011), *aff'd. per curiam,* 463 Fed. Appx. 932 (Fed. Cir. 2012) (specifying that each *Althen* factor must be established by preponderant evidence). The preponderance of the evidence standard, in turn, has been interpreted to mean that a fact is more likely than not. *See Moberly v. Sec'y of HHS,* 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. *Bunting v. Sec'y of HHS*, 931 F.2d 867, 873 (Fed. Cir. 1991).

The Federal Circuit in *Althen* noted that "while [Althen's petition] involves the possible link between [tetanus toxoid] vaccination and central nervous system injury, a *sequence hitherto unproven in medicine,* the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field *bereft of complete and direct proof of how vaccines affect the human body." Althen*, 418 F.3d at 1280 (emphasis added).

[7] A "Table" injury is an injury listed on the Vaccine Injury Table, 42 C.F.R. § 100.3 (2014), corresponding to the vaccine received within the time frame specified.

Once petitioner establishes each of the *Althen* factors by preponderant evidence, the burden of persuasion shifts to respondent, who must show that the alleged injury was caused by a factor unrelated to the vaccination. *Knudsen v. Sec'y of HHS*, 35 F.3d 543, 548 (Fed. Cir. 1994); § 13(a)(1)(B). Respondent must demonstrate that "the factor unrelated to the vaccination is the more likely or principal cause of the injury alleged. Such a showing establishes that the factor unrelated, not the vaccination, was 'principally responsible' for the injury." *Deribeaux v. Sec'y of HHS*, 717 F.3d 1363, 1369 (Fed. Cir. 2013). Section 13(a)(2) specifies that factors unrelated do "not include any idiopathic, unexplained, unknown, hypothetical, or undocumented causal factor, injury, illness, or condition." Close calls regarding causation must be resolved in favor of the petitioner. *Althen*, 418 F.3d at 1280.

In determining whether petitioner is entitled to compensation, a special master must consider the entire record and is not bound by any particular piece of evidence. § 13(b)(1) (stating a special master is not bound by any "diagnosis, conclusion, judgment, test result, report, or summary" contained in the record). Thus a special master must weigh and evaluate opposing expert opinions, medical and scientific evidence, and the evidentiary record in deciding whether petitioners have met their burden of proof. "Although *Althen* and *Capizzano* make clear that a claimant need not produce medical literature or epidemiological evidence to establish causation under the Vaccine Act, where such evidence is submitted, the special master can consider it in reaching an informed judgment as to whether a particular vaccination likely caused a particular injury. . . . Medical literature and epidemiological evidence must be viewed, however, not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Andreu v. Sec'y of HHS*, 569 F.3d 1367, 1380 (Fed. Cir. 2009).

B. The Parties' Contentions Regarding Entitlement

There is no dispute that petitioner received a covered vaccine, the flu vaccine, in the United States at his family physician's office in New York on September 14, 2011. The parties also agree that the petitioner suffered and continues to suffer from an autoimmune disease with an onset date after the receipt of the vaccine. Thus, there is no dispute that he has suffered the symptoms of the claimed disease for more than six months. There is disagreement, however, about the diagnostic entity of that disease and the date of onset of the classical autoimmune disease.

In addition to comprehensive medical records, the parties presented expert testimony and filed significant medical literature to support their contentions. Petitioner presented the testimony of Vera Byers, M.D., Ph.D., and the respondent presented the testimony of Chester V. Oddis, M.D., in opposition.

i. Expert Credentials

1. Vera Byers, M.D., Ph.D.

Petitioner's expert, Dr. Byers, obtained her undergraduate degree from the University of California Los Angeles (UCLA), and then obtained a masters and Ph.D. in microbiology and

immunology from the same institution. Tr. at 42. She then attended medical school at the University of California San Francisco (UCSF). *Id*. She did a residency in internal medicine and a fellowship in clinical immunology and protein chemistry, and has also taken training in clinical research and statistics. *Id*. She was one of the four founders of the field of tumor immunology, in which she began work in 1971 to look for ways to find immunotherapeutic treatments for cancer. *Id*. at 43. In addition, she was the inventor of the first monoclonal antibody for use in humans and has since invented about ten monoclonal antibodies for various therapies. *Id*.

She began working with vaccines in 1968, investigating how they could be used to treat autoimmune diseases, and ran clinical trials to investigate the use of vaccines in multiple sclerosis. Tr. at 44. She is a member of multiple medical societies, with her main focus being in the Clinical Immunology Society. *Id*. at 46. She has done work in the Vaccine Court since 1985, addressing the issues of the immune system effect on the nervous system. *Id*. at 45. In her practice, she has dealt with individuals with Sjogren's syndrome, arthritis, polyarthritis, polymyositis, and other conditions that are involved in this case. *Id*. at 46. She was offered as an expert in the field of immunology, particularly as it relates to whether vaccines can be a trigger or substantial factor in causing autoimmune disease. *Id*. at 48. Without objection, she was admitted as an expert in this field. *Id*.

2. Chester V. Oddis, M.D.

Dr. Chester Oddis testified on behalf of respondent. Dr. Oddis obtained his degree at the University of Pittsburgh and then attended medical school and did his residency and chief residency at Penn State University. Tr. at 131. Subsequently, he returned to the University of Pittsburgh to complete a fellowship and then joined the medical faculty in 1987, where he is now a professor of medicine and the director of the Myositis Center. *Id*. at 131-32. He is a specialist in myositis and spends about forty percent of his time in clinical practice, forty percent in research, and twenty percent teaching. *Id*. He was the principle investigator in the largest NIH funded trial of myositis. *Id*. at 136. In addition, he treats anti-synthetase syndrome, overlap syndromes, and has treated carpal tunnel syndrome. *Id*. at 133-34. He testified that both anti-synthetase and the overlap syndromes are "rare birds" but that the overlap syndromes are a bit more frequent than the anti-synthetase syndrome. *Id*. at 134. Carpal tunnel syndrome on the other hands is quite common. *Id*. Without objection, he was admitted as an expert in the field of rheumatology. *Id*. at 136-37, 39.

ii. Petitioner's Expert Testimony

Dr. Byers agreed with multiple treating medical specialists in rheumatology and neurology that Mr. Rodd initially experienced symptoms of carpal tunnel syndrome, which were ultimately relieved by carpal tunnel surgery, and that he went on to develop overlap syndrome beginning approximately a month after receipt of the flu vaccine. *See* Pet. Ex. 6 at 000002; Tr. at 82-83. In addition to the clinical symptoms of polyarthritis and polymyositis described above, the basis of the diagnosis of overlap syndrome was the presence of the SSA antibody, typical of Sjogren's, initially recognized in the October 21, 2011 blood work and the anti-Jo-1 antibody

and elevated aldolase seen in the December 5, 2011 blood work.[8] Pet. Ex. 3 at 000005 (October 21 blood work); Pet. Ex. 8 at 00099 (December 5 blood work).

Dr. Byers explained that Mr. Rodd likely had a developing but asymptomatic carpal tunnel syndrome at the time that he received the flu shot. Tr. at 72-73. She said it was likely that secondary to his occupation, his carpal tunnel was already narrowed and on the verge of becoming symptomatic, and the additional inflammation caused by the innate response to the flu shot made it symptomatic. *Id*. She said that the cytokines released by the flu shot likely reacted to a new antigen or cryptotope[9] presented by irritated tissue in the carpal tunnel. *Id*. at 76-77. She explained that this cytokine response was a function of the innate immune system, which caused additional inflammation at the carpal tunnel sufficient to make it symptomatic. *Id*. at 71-73. She explained that the expected rapid response of the innate immune system would explain the early carpal tunnel symptoms and she submitted three papers that supported the phenomena of cytokines, in particular IL-1 and IL-2, causing inflammation and entrapment of the median nerve, which caused it to become symptomatic in the carpal tunnel. *Id*. at 73-76. For example, a study of patients receiving IL-2 therapy demonstrated the early onset of carpal tunnel syndrome after infusion.[10] The fact that the symptoms of numbness and tingling in the thumbs and fingers were relieved by the carpal tunnel release surgery provided confirmation of carpal tunnel. *Id*. at 68.

If Mr. Rodd had only suffered an innate cytokine response, which caused his underlying carpal tunnel syndrome to become symptomatic, he likely would have become completely better after the surgery. Indeed, he had relief of those symptoms that were particular to carpal tunnel syndrome after the surgery. Tr. at 67-68, 105. However, he developed significantly more symptoms beginning several weeks after the vaccine, which progressed for a considerable period of time and that were different from the original symptoms. *See Id.* at 26-29. He began to experience weakness in the arms and shoulders, followed by the neck, hips and thighs. *Id.* He developed multiple functional impairments such as difficulty transferring, dressing, gripping, and lifting. *Id.*; Pet. Ex. 5 at 000001. When he saw Dr. Horowitz, he was described as having profound muscle weakness primarily in the proximal distribution as well as xerostomia (dry mouth). Pet. Ex. 5 at 000001. He developed what Dr. Horowitz called, and Dr. Byers agreed, was polyarthritis, polyarthralgia and polymyositis. *Id*. at 000002; Tr. at 82-83. These clinical symptoms together with the laboratory signs of overlapping autoimmune disease provided what Dr. Horowitz called "overwhelming evidence for an overlap syndrome with features of polymyositis, Sjogren's syndrome and inflammatory arthritis." Pet. Ex. 5 at 000002. Dr. Horowitz stated that "[t]he positive anti-Jo-I antibody, the history of the positive Sjogren's antibodies and the persistent elevations of the CPK and aldolase levels all support this diagnosis." *Id*. Dr. Byers agreed. *See* Tr. at 82-83. Dr. Horowitz further noted that Mr. Rodd

[8] The anti-Jo-1 antibody was not tested in the earlier blood work that found the SSA antibody. *See* Pet. Ex. 3 at 000005-7.

[9] A cryptotope is a "hidden antigen which is then unveiled with trauma." Tr. at 100.

[10] Vinay K. Pudavalli et al, *Carpal Tunnel Syndrome Associated with Interliukin-2 Therapy*, 77 CANCER 6, 1189 (1996).

was "profoundly weak and completely disabled for performing his occupation, as well as activities of daily living." Pet. Ex. 5 at 000002.

Dr. Byers opined that the autoimmune disease was a new entity with a date of onset in the middle of October, 2011. Tr. at 84. The first evidence for autoimmune diseases was the positive SSA together with dry mouth and developing muscle weakness or polymyositis in the arms and shoulders. *Id*. at 61, 84. When he saw Dr. Ashraf, a rheumatologist, on December 5, 2011, the doctor diagnosed Sjogren's (also called Sicca syndrome) based on the elevated SSA and dry mouth and polyarthritis (pain in multiple joints), and myalgias (pain or weakness in multiple muscles). *Id*. at 65. She then tested for other autoimmune antibodies and discovered the anti-Jo-1 antibody and elevated aldolase. *Id*. at 66.

Dr. Byers explained that the innate cytokine response is very quick and non-specific, while the adaptive response takes from four days to several weeks to produce specific antibodies and T cells responsive to the foreign antigen in the flu shot. Tr. at 59-60. After production, there is a period of several days over which the T cells begin to chew at the joints to produce autoimmune symptoms. *Id*. at 60. Dr. Byers submitted various articles describing potential autoimmune mechanisms of injury that could be responsible for the production of polyarthritis and polymyositis. *Id*. at 99-100. These mechanisms included molecular mimicry, bystander activation, antigenic spreading, and cryptotope production, which would be the unmasking of an antigen that the body had not seen before. *Id*. She thought that the latter three mechanisms were more likely than molecular mimicry to be the cause of Mr. Rodd's disease. *Id*. at 101.

She explained that antigenic spreading is where T cells or B cells attack one or a few amino acids on a protein and spread to others in the body over time. Tr. at 101. Bystander activation is when you have a cell, such as a T cell, that normally is fairly benign, but produces a lot of cytokines when stimulated. *Id*. at 102. These cytokines then activate and attract other less specific T cells, which otherwise would not produce damage, but produce damage once activated and allowed to mature. *Id*.

Dr. Byers agreed with the treating physicians that Mr. Rodd developed an overlap syndrome beginning several weeks following the flu vaccination and the onset of his carpal tunnel symptoms. She opined that the vaccination was likely the cause of the overlap syndrome. Tr. at 104. She was persuaded of this by the mechanisms that reasonably explained the symptoms and the development thereof, the fact that vaccines have often been associated with the range of autoimmune diseases, and the timing of the onset of the condition, which was well within an explained and expectable time period. *Id*.

iii. Respondent's Expert Testimony

Dr. Oddis, a myositis specialist, disagreed with the diagnosis of overlap syndrome and instead believed that Mr. Rodd suffered from anti-synthetase syndrome based upon the finding of the anti Jo-1 antibody. Tr. at 140. He testified that the presence of that antibody makes the diagnosis of anti-synthetase syndrome, and that it is not unusual for the SSA or RO-52 antibody to occur in conjunction with the anti-Jo-1 antibody. *Id*. at 146, 154-55. In fact, the literature he submitted suggests that antiRo or anti SSA (the same antibody) antibodies co-occur in as many

as fifty-eight percent of anti-JO-1 anti-synthetase patients. Resp. Ex. D at 1; Resp. Ex. E at 1, 7; *see also*, Resp. Ex. F at 1; Resp. Ex. G at 6. He also did not believe that the vaccine caused the syndrome in petitioner. Tr. at 140. He explained that to make the diagnosis of anti-synthetase syndrome the patient must have one of eight antibodies against one of the amino acetyl tRNA enzymes, in this case the anti Jo-1 antibody. *Id*. at 141. The disease involves myositis, interstitial lung disease, polyarthritis or inflammatory joint pain, Reynaud's phenomena, fever, and mechanic's hands, but patients may not have all six symptoms. *Id*. at 141-42. Mr. Rodd did not have all six symptoms and thus Dr. Oddis diagnosed "incomplete" anti-synthetase syndrome. *Id.* at 171-72. Dr. Oddis testified that synthetase is a ubiquitous enzyme that is floating in the body, and is an amino acetyl tRNA enzyme that grabs an amino acid in the process of protein synthesis. *Id*. at 142-43. He believed that Mr. Rodd's body "went haywire" and produced an antibody to this common enzyme, which is what autoimmunity does. *Id*. at 143.

Overlap syndrome, according to Dr. Oddis, requires clinical features of at least two different autoimmune or connective tissue diseases, such as lupus and scleroderma. Tr. at 144-45. Anti-synthetase symptoms are specific to that disease entity, while overlap syndrome can be diagnosed based upon whatever two conditions are present, including Sjogren's syndrome. *Id*. at 145. Both are rheumatic diseases and both evolve over time. *Id*. at 145-46. Dr. Oddis said that it is the presence of a particular antibody, in this case the anti-Jo-1 antibody, that makes anti-synthetase syndrome distinct. *Id*. at 146.

The petitioner did not have all of the manifestations of anti-synthetase syndrome, but did have at least the dry mouth manifestation of Sjogren's syndrome. Mr. Rodd had dry mouth but not dry eyes. Tr. at 65. Dr. Oddis stated that dry mouth without dry eyes does not support a diagnosis of Sjogren's syndrome. *Id.* at 155-56. However, consistent with the literature submitted, Dr. Oddis admitted on cross-examination that the current literature only requires one or the other. *Id*. at 208-9. Dr. Oddis testified that it was his understanding that the literature defining the criteria for Sjogren's was being re-evaluated to require both dry eyes and dry mouth but that this modification had not yet been published in any peer reviewed journals and had not yet been agreed upon by the criteria committee. *Id*. at 210. He said he understood, but disagreed with, Dr. Horowitz's diagnosis of overlap syndrome based on the presence of the anti-Jo-1 antibody in addition to the Sjogren's antibody, SSA. *Id*. at 193. He believed that the co-appearance of these antibodies was more likely a manifestation of anti-synthetase syndrome and not two separate disease entities. *Id*. at 161. He said that he was not qualified to testify as to whether the cytokines released in response to a vaccine could aggravate symptoms in a pre-existing entrapment neuropathy such as carpal tunnel syndrome. *Id*. at 197. However, he did agree that the Physician's Desk Reference says that transient myopathies are common after vaccines and that it is possible that they may have an impact on a pre-existent condition like carpal tunnel. *Id*. at 198.

There was considerable debate during the testimony about the nature of the early symptoms, and whether the diagnosis rendered by the treating physicians and Dr. Byers—carpal tunnel syndrome followed several weeks later by overlap syndrome—was correct, or whether Dr. Oddis was correct that the diagnosis was necessarily anti-synthetase syndrome based on the presence of the anti-Jo-1 antibody together with the SSA antibody. However, Dr. Oddis agreed on cross-examination that the specific diagnosis of the autoimmune entity was completely

irrelevant to his opinion on causation. Tr. at 195-96. His opinion as to causation was based on his view that the symptoms Mr. Rodd experienced on the first day after the vaccination represented the presentation of polyarthritis, which he thought was part of the anti-synthetase syndrome. *Id*. at 147, 203. He said that he believes the first symptom of anti-synthetase syndrome was inflammatory joint pain that affected Mr. Rodd's hands. *Id*. at 147. He acknowledged that the first positive evidence for autoimmune disease was the finding of the SSA antibody for Sjogren's on October 21, 2011, approximately five weeks after the vaccination. *Id*. at 147-48. He also agreed that Mr. Rodd had electro-diagnostic evidence of carpal tunnel on November 11, 2011, that he experienced relief of the symptoms of numbness and tingling in the hands and wrists from the carpal tunnel release surgery, and that therefore he had elements of carpal tunnel syndrome. *Id*. at 201. However, Dr, Oddis still opined that the early symptoms, which he described as including swelling and joint pain in the fingers, but which the petitioner did not describe as such and which his physicians did not observe or document as such, were consistent with the early development of anti-synthetase syndrome. *Id*. at 203-4. Because he thought that the autoimmune, anti-synthetase syndrome explained the day one symptoms, which he called polyarthritis, he thought that onset was too soon to attribute causation to the vaccine. *Id*. at 199.

C. Analysis

As the parties agree that whether Mr. Rodd's diagnosis is overlap syndrome or anti-synthetase syndrome is irrelevant to their positions on vaccine causation, the essence of the dispute is the characterization of the initial symptoms and the timing of the onset of the auto-immune component of the disease, regardless of whether it is overlap syndrome or anti-synthetase syndrome.

i. *Althen* Prong I

Dr. Byers proposed the theory that the initial bilateral symptoms in Mr. Rodd's hands were generated by a rapid innate immune, cytokine response to the vaccine. She theorized that the cytokines stimulated by the vaccine were rapidly drawn to already irritated but asymptomatic tissue in the carpal tunnel, producing enough inflammatory response to make the condition symptomatic. Tr. at 70-73. The second and more critical part of her theory was that the adaptive immune response to the vaccine began to cause symptoms four to five weeks after the vaccination in the form of weakness in the arms and shoulders. *See* Tr. at 84. These symptoms progressed, ultimately involving the shoulders, arms, neck, hips, thighs, and feet, and was diagnosed as overlap syndrome based on Sjogren's syndrome together with the polymyositis (weakness) and polyarthritis (joint pain) that developed secondary to the adaptive response to the vaccine. *Id.* at 82-83; Pet. Ex. 3 at 000005. Dr. Byers contended that the adaptive response likely involved antigenic spreading, where T cells and B cells over time attack an increasing number of amino acids, or bystander activation, where normally benign T helper cells produce a lot of cytokines which attract other less specific T cells that become activated and produce damage. Tr. at 101-102. Thus, her testimony explained both phases of Mr. Rodd's disease.

Dr. Oddis believed that the initial symptoms were caused by polyarthritis in the hands. Tr. at 147. He agreed that the polymyositis and polyarthralgia were autoimmune conditions

caused by an adaptive immune response, but thought that an adaptive immune response the day following the vaccine would be too fast. *Id*. at 184-85, 199. He said that he was not qualified to testify as to whether an innate, cytokine response could cause symptoms of carpal tunnel syndrome, and had a difficult time explaining the occurrence of carpal tunnel syndrome particularly as he acknowledged that Mr. Rodd would not have gotten relief from those symptoms from the carpal tunnel surgery if he did not have carpal tunnel syndrome. *Id.* at 197. In essence, Dr. Oddis based his opinion of causation on his conclusion that the initial symptoms were part of the ultimate autoimmune disease, which he believed is anti-synthetase syndrome, and that the onset shortly after the vaccine was essentially a coincidence.

I have concluded, in part through the Althen II and III analyses below, that Dr. Byers' opinion reasonably accounts for the early carpal tunnel symptoms as well as the later occurring polymyositis and polyarthralgia. Dr. Oddis, on the other hand, discounted carpal tunnel as an explanation for the early symptoms even though the diagnosis was confirmed by Tinel's test, and ultimately by carpal tunnel surgery. Dr. Byers' two part theory of causation in this case better tracked the development of Mr. Rodd's symptoms, and provided a reasonable explanation of the timing of both.

ii. *Althen* Prong II

Dr. Byers agreed with the treating physicians that Mr. Rodd experienced symptoms of carpal tunnel syndrome on the day after the vaccination. Tr. at 55. Indeed, Mr. Rodd's symptoms were quite consistent with carpal tunnel syndrome, which is a very common entrapment disorder in which the median nerve becomes irritated and symptomatic either from swelling or inflammation of the median nerve or narrowing of the tunnel through which the median nerve passes at the wrist. *See id*. at 55-56. The median nerve and nine flexor tendons pass through the carpal tunnel in the wrist. Flexor tendons help with flexion or bending of the fingers and their compression would be consistent with Mr. Rodd's inability to close his fingers. When the median nerve is compressed by swollen tissue it slows or blocks the conduction of nerve impulses and impairs both sensory and motor function in the hand.[11] The primary symptoms of carpal tunnel syndrome are numbness and tingling in the thumb and fingers. *See id.* at 164. The syndrome is thought to have multiple causes, but heavy lifting and other occupational and repetitive stresses on the hand are likely to be among the most common, as Dr. Oddis agreed. *Id*. at 200. Dr. Byers testified that Mr. Rodd, due to the heavy work entailed in his occupation, was likely on the verge of becoming symptomatic when he had his flu shot. *Id*. at 72-73. In other words, the passageway for the median nerve and flexor tendons through the carpal tunnel were likely already narrowed, but not yet to the point of causing symptoms. She explained that the inflammatory cytokine response to the vaccine generated by the innate immune system within hours of the vaccination was likely attracted to the already irritated tissue, causing further inflammation and swelling in the narrow tunnel, and thereby producing the symptoms that Mr. Rodd experienced in the initial days and weeks after the flu shot. *Id*. at 71-72.

[11] *Carpal Tunnel Syndrome*, AMERICAN COLLEGE OF RHEUMATOLOGY, www.rheumatology.org/Practic/Clinical/Patients//Diseases_And _Conditions/Carpal_Tunnel_Syndrome.

On the other hand, Dr. Oddis thought that the early symptoms represented the onset of polyarthritis as part of the anti-synthetase syndrome, as he testified that polyarthritis is often the presenting symptom of anti-synthetase syndrome. Tr. at 162-63; *Id*. at 203. He thought Mr. Rodd testified that he had puffiness and swelling in his fingers and pain in his hands, which would be atypical for carpal tunnel syndrome. *Id*. at 164. However, careful review of the transcript reveals that Mr. Rodd described tingling just in the tips of his fingers and thumbs the morning after the vaccination, but nothing significant. *Id.* at 12. The next day after driving equipment his hands were really numb when removed from the steering wheel. *Id*. In his first appointment post flu shot on October 18, 2011, Dr. Walker noted that Mr. Rodd described initially having difficulty using his hands, which was worse at night and better during the day, but no swelling, neck pain, injury or trauma, and decreased finger range of motion and grip strength, but no edema. Pet. Ex. 1 at 000003-4. The numbness and tingling in the fingers and thumbs, worse at night and after driving, with decreased grip strength are all classic symptoms of carpal tunnel syndrome.[12] At the October 18, 2011 appointment with Dr. Walker, thirty five days after the flu shot, there was no report of swelling, puffiness or pain, and none was observed on examination by the doctor. *See* Pet. Ex. 1. There was no report of any symptoms above the wrist at the October 18 appointment. *Id*.

Dr. Walker referred Mr. Rodd to Dr. Kucherov, a neurologist, who observed a positive Tinel's test—a test for carpal tunnel syndrome. Pet. Ex. 3 at 000004. Dr. Kucherov ordered an EMG, which showed mild to moderate median sensorimotor neuropathy at the level of the wrist bilaterally (carpal tunnel syndrome) without acute or chronic axonal loss. *Id*. at 00010.

Most significantly, petitioner underwent carpal tunnel release surgery on both wrists, which provided relief from the numbness and tingling in the hands and wrists. Tr. at 30-1, 67-8. The doctor who performed the surgery told Mr. Rodd that the carpal tunnel probably arose after the flu shot because the shot likely exacerbated a condition that already existed from manual labor, by squeezing the nerve in the wrist or constricting the hole. *Id*. at 31-2. Dr. Byers noted that carpal tunnel release is very specific surgery, and the fact that Mr. Rodd had relief from the carpal tunnel symptoms after the surgery confirmed that he had carpal tunnel syndrome. *Id*. at 69.

The fact that the early symptoms appeared to be most consistent with carpal tunnel syndrome and the fact that those symptoms were ultimately relieved by carpal tunnel surgery makes Dr. Byers' explanation more persuasive than Dr. Oddis' opinion as to the diagnosis of the early symptoms. Importantly, Dr. Byers explained the early onset as attributable to a rapid response of the innate immune system to likely already irritated median nerves in the wrist. Dr. Byers' theory provides a persuasive explanation for how the cytokine response triggered by the flu vaccine caused the initial carpal tunnel symptoms, and explains the early onset of these symptoms in a manner consistent with the testimony and medical records of the early symptom presentation.

[12] *Health Library: Carpal Tunnel Syndrome*, JOHNS HOPKINS MEDICINE, http://www.hopkinsmedicine.org/healthlibrary/conditions/adult/arthritis_and_other_rheumatic_diseases/carpal_tunnel_syndrome_85,P00048/.

The heart of the case, however, involves the adaptive immune response producing what was described by the treating physicians as overlap syndrome and diagnosed by Dr. Oddis as anti-synthetase syndrome. Those symptoms began to become evident in late October or early November, 2011, and became more evident by the time that Mr. Rodd was referred to a rheumatologist (Dr. Ashraf) in December. Mr. Rodd descrived the initial symptoms in his hands as just pins and needles, and were no comparison to the pain and weakness that followed. Tr. at 29. He used to be able to lift four fifty-pound feed bags at once but now his wife has to lift even one for him. *Id*. He was referred to Dr. Ashraf in early December, and Dr. Ashraf initially diagnosed Sjogren's syndrome or Sicca Syndrome based on Mr. Rodd's elevated SSA antibodies and dry mouth. Pet. Ex. 4 at 000002. She subsequently ordered testing for anti-Jo-1 antibodies, which was also positive. Pet. Ex. 8 at 00096. Dr. Oddis testified that he believes that the anti-Jo-1 antibodies would also have been positive at the time of the SSA testing, had they been ordered then, rather than sequentially, as occurred. Tr. at 154. He said that it is common in anti-synthetase syndrome to have both positive SSA and anti-Jo-1 together. *Id*. at 146, 154-55. He thought that Mr. Rodd's early symptoms were part of the anti-synthetase syndrome, which progressed to the shoulders, arms and legs. Tr. at 161. He did agree that Mr. Rodd did not have all of the symptoms of anti-synthetase syndrome as he did not have Reynaud's or mechanic's hands, and at most had a very mild interstitial lung disease, which is usually a major element of anti-synthetase syndrome. Tr. at 172.

Dr. Byers explained her opinion that several weeks after the flu shot, probably by the beginning of November, 2011, Mr. Rodd was beginning to experience the symptoms of polyarthritis and polymyositis, which by December were diagnosed by a rheumatologist as such and given the name overlap syndrome due to their concurrence with Sjogren's. By July of 2012, he was sent to see Dr. Horowitz in New York City, a specialist in myositis. Dr. Horowitz evaluated him and wrote that he had "overwhelming evidence for overlap syndrome with features of polymyositis, Sjogren's syndrome and inflammatory arthritis." Pet. Ex. 5 at 000002.

Dr. Byers' testimony was more consistent and more persuasive than Dr. Oddis' in that she provided a cogent explanation for both the early onset carpal tunnel syndrome and the subsequently occurring overlap or anti-synthetase syndrome. She delineated the role of the innate immune system and the cytokine response in generating carpal tunnel symptoms from the adaptive B and T cell role in causing the autoimmune disease several weeks later. Tr. at 60. There is little question that Mr. Rodd clearly described significantly different symptoms occurring in late October or early November and thereafter from those that occurred in the initial days after the flu shot. Her testimony was consistent with the records of multiple treating physicians, including a neurologist and two rheumatologists—one a specialist in myositis. While Dr. Oddis is recognized as a major specialist in myositis and may well be correct as to the nature of the disease being anti-synthetase as opposed to overlap, it appears from the literature to be a close call and one that does not make a difference to the issue of vaccine causation. Dr. Oddis ultimately clarified that his opinion as to vaccine causation was based upon his opinion that the autoimmune disease began on the day after the flu vaccine, which both experts agree would have been too soon. However, he could not explain the carpal tunnel syndrome and agreed that the petitioner would not have experienced relief from the surgery if he did not have carpal tunnel syndrome. Tr. 198-203. He was left to speculate that Mr. Rodd may have gotten carpal tunnel later, even though the early symptoms were entirely consistent with carpal tunnel and not very

consistent with polyarthritis. *Id.* at 198-200. He did agree that Mr. Rodd's immune system "went haywire" and produced an antibody to the synthetase enzyme. *Id.* at 142-143. He also agreed with Dr. Byers that the B cells and T cells play an important role in causing this syndrome, but he found it hard to make that "leap of faith" in this case. *Id.* at 177-78.

Proof of *Althen* Prong II requires a logical explanation as to how the vaccine did cause the injury in the petitioner. "'A logical sequence of cause and effect' means what it sounds like—the claimant's theory of cause and effect must be logical." *Capizzano,* 440 F.3d at 1326. The proof need not rise to the level of scientific certainty but rather to the Vaccine Act's preponderance standard under the system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." *Andreu,* 569 F.3d at 1378 (quoting *Capizzano,* 440 F.3d at 1325-26). The testimony of a treating physician is "favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" *Capizzano,* 440 F.3d 1317 at 1326. A treating physician may rely on the close temporal proximity between a vaccine and an injury in concluding that there is a logical sequence of cause and effect between the vaccine and the injury. *Id.* at 1326.

In this case, the treating physicians diagnosed and treated carpal tunnel syndrome with success and subsequently diagnosed an overlap syndrome. Several treating physicians told Mr. Rodd that his condition probably had to do with the flu vaccine. Tr. at 40. Specialists in the field of rheumatology diagnosed his autoimmune condition as overlap syndrome. Dr. Byers provided a logical explanation for both the early onset of the carpal tunnel symptoms caused by the rapid inflammatory cytokine response to the vaccine, and for the subsequent autoimmune disease that had its onset about a month after the vaccine and was caused by the slower activation of the adaptive immune system. The timing for both of her explanations is reasonable.

Dr. Oddis' expertise in the field of myositis is given deference, however, he was unable to provide a reasonable explanation for the onset of the carpal tunnel syndrome and ascribed symptoms of joint pain and swelling to Mr. Rodd on the first day post vaccination. This attribution was not consistent with either the testimony or the medical records. While he may be correct that the later diagnosis should be called anti-synthetase syndrome as opposed to the overlap syndrome diagnosed by the treating rheumatologists, by his own testimony it was made clear that the nature of the diagnosis was irrelevant to his opinion on causation. The essence of his opinion was based upon his attribution of symptoms of joint pain and swelling on the first days after the vaccination, which he called the early presentation of polyarthritis. As noted above, neither the testimony nor Dr. Walker's records supported that description of the early symptoms. The joint pain and swelling became part of the picture in late October or early November.

iii. *Althen* Prong III

For the reasons recited above, I have concluded that Dr. Byers' theory reasonably accounts for both the early onset carpal tunnel symptoms and the later onset autoimmune disease. She testified that it is probable that a rapid inflammatory cytokine response to the vaccine was drawn to the already irritated carpal tunnel area causing sufficient inflammation for

an asymptomatic condition to become symptomatic. Tr. at 72-73. She further testified that four days to several weeks was necessary for the B cell and T cell adaptive response to occur, and it would take some time after that for them to start producing autoimmune damage. *Id.* at 93.

Dr. Oddis essentially agreed with the timing necessary for an adaptive immune response, but contended that Mr. Rodd's autoimmune disease began the day after the vaccine. As I have concluded that the adaptive autoimmune component of the disease began to become symptomatic roughly a month to five weeks after the vaccination, I find that the timing is appropriate.

Althen requires the petitioner to provide an explanation of how the vaccine could cause his symptoms, a logical explanation for how it did, and an explanation as to the appropriateness of the timing of onset. I have concluded that Dr. Byers has done this, and has logically explained all of the elements of Mr. Rodd's symptom progression in accord with the documentation of his symptom progression. Accordingly, I have concluded that the petitioner is entitled to compensation.

IV. Conclusion

The petitioner has prevailed on the issue of entitlement. The undersigned will schedule a telephonic status conference to discuss resolution of damages.

IT IS SO ORDERED

s/ Thomas L. Gowen
Thomas L. Gowen
Special Master